DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert S. Quandt, President
Quandt's Foodservice Distributors, Inc.
105 Quist Road
Amsterdam, NY 12010

August 13, 2002

Ref: NYK-2002-43

Dear Mr. Quandt:

We inspected your seafood processing facility, located at the above address, on July 15 and 16, 2002 and found that you have serious deviations from the Seafood HACCP regulations (Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)). These deviations, some of which were previously brought to your attention, cause your refrigerated canned pasteurized crabmeat and refrigerated pickled herring products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through the links in FDA's home page at www.fda.gov.

The deviations included, but are not limited to, the following:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated canned pasteurized crabmeat to control the food safety hazard of *Clostridium botulinum* toxin formation as a result of time/ temperature abuse.

2. You must implement the monitoring procedures and record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of taking and recording the incoming temperature of product at the receiving critical control point to control the pathogen growth/ *Clostridium botulinum* toxin formation hazards listed in your HACCP plan for refrigerated pickled herring products.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

For your information, the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition* (see www.fda.gov) recommends several acceptable time/temperature monitoring procedures for receiving ready-to-eat fishery products to be stored or processed without further cooking. These include monitoring: the internal temperature of the product throughout transportation; or the temperature of the truck throughout transportation; or (for products with a transit time of four hours or less) the internal temperature of a representative number of containers at time of delivery; or the adequacy of ice or chemical cooling media at time of delivery (if applicable).

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Forms FDA 483) issued to and discussed with Jason D. Wilson, Seafood Specialist at the conclusion of the inspection may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

Jerome G. Woyshner
District Director

Enclosures: Forms FDA 483 dated July 16, 2002